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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,610	02/12/2001	Jonathan Stanley Harold Denyer	102199-100	3883

7590 11/21/2003

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EXAMINER	
MENDOZA, MICHAEL G	
ART UNIT	**PAPER NUMBER**
3761	

DATE MAILED: 11/21/2003 18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/781,610	DENYER ET AL.	
	Examiner	Art Unit	
	Michael G. Mendoza	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-13 and 15-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-13 and 15-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 and 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. In claim 1, the Applicant is required to clarify to what the claim is intended to be drawn to, i.e., either the plurality of drug vials and electronic data carrier alone or the combination of the plurality of drug vials, the electronic data carrier and the drug delivery device. The Applicant sets forth the combination of the plurality of drug vials, electronic data carrier and the drug delivery device when describing the structure associated with the delivery device (see claim6), which is inconsistent with claim 1, that sets forth the subcombination of the plurality of drug vials and the electronic data carrier. Applicant is required to make the language of the claims consistent with the intent of the claims. It should also be noted that in considering the claims on the merits, the Examiner will consider the claims as drawn to the combination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 6, 7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Castellano et al. 5593390.

6. Castellano et al. teaches a drug package comprising: a plurality of drug vials; an electronic data carrier separate from the drug vials, the carrier including drug treatment information (col. 9, lines 15-26); wherein the data carrier is arranged to include at least one of the following items of treatment information: the dose of drug to be delivered; the identity of the drug which is to be delivered; the expiry date of the drug to be delivered; and the number of treatments available from the drug package (col. 6, lines 6-22); wherein the drug vials contain drugs adapted for delivery in air inhaled by a patient to their lungs; wherein the drugs vials are arranged to be used in conjunction with a drug delivery device (col. 2, lines 52-56), wherein the data carrier is arranged to transfer treatment information to a drug delivery device when it is moved to a receptive surface or region of the drug delivery apparatus 446; wherein the data carrier is arranged to supply drug treatment information to a drug delivery device a number of times corresponding to the number of treatments available from the drug package, or the number of vials included in the drug packages (col. 2, lines 59-67); wherein the data carrier is a radio frequency device; and wherein the data carrier includes a memory for recording information concerning treatments received from the drug delivery device.

7. Claims 13, 15, 16, 18, 20, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Castellano et al.

8. Castellano teaches a drug delivery apparatus comprising: a delivery portion 28; an electronic input (col. 9, lines 15-26); a delivery controller; wherein the input is a radio

frequency input which receives the treatment information from a data carrier at radio frequency (col. 9, lines 15-26); wherein the input is additionally arranged to transmit completed treatment information to the data carrier (col. 9, lines 15-26); wherein the drug delivery apparatus is one of a pneumatic nebulizer, a piezo-electric nebulizer and an ultrasonic nebulizer (col. 23, lines 9-12); and a medication chamber 16.

9. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Wolf et al. 5505195.

10. Wolf et al. teaches an electronic data carrier for use with a drug delivery apparatus comprising a memory located within the data carrier for holding treatment information concerning the use of the drug delivery apparatus in delivering a specified drug, and an output for transmitting treatment information to the drug delivery apparatus (col. 11, lines 41-58).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Castellano et al. in view of Wolf et al.

13. Castellano et al. teaches the drug delivery apparatus according to claim 13. It should be noted that Castellano et al. fails to teach wherein the drug delivery apparatus includes an authorization portion which prevent delivery if any of the treatment

information indicates that the drug is unsuitable for delivery. However, Wolf et al. teaches wherein the drug delivery apparatus includes an authorization portion which prevents delivery if any of the treatment information indicates that the drug is unsuitable for delivery. Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Castellano et al. to include the authorization portion of Wolf et al. to insure proper activation (col. 11, lines 24-34).

14. Claims 22-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al. in view of Eigler et al. 6328699.

15. As to claim 22, Wolf et al. teaches a drug deliver device comprising:

a delivery portion for delivering a drug to a patient 140;

a drug use analyzer which records the use of the drug over a number of treatments as recorded treatment information, which analyses to amount of a drug delivered over a number of treatments and which identifies when only a certain proportion of the prescribed drug remains (col. 13, line 52-67). It should noted that Wolf et al. fails to teach a repeat prescription ordering portion which operates to submit the recorded treatment information to a data center once the drug use analyzer identifies that less than the certain proportion of the prescribed drug remains, the data center analyzing the recorded treatment information according to a protocol in order to formulate a result that identifies whether certain specifications are satisfied and, where the result indicates that the certain specifications have not been satisfied, referring the patient to a doctor, the doctor treating the patient. However, Eigler et al. does teach a repeat prescription ordering portion (col. 10, lines 60-65) which operates to submit the recorded treatment

information to a data center once the drug use analyzer identifies that less than the certain proportion of the prescribed drug remains, the data center analyzing the recorded treatment information according to a protocol in order to formulate a result that identifies whether certain specifications are satisfied and, where the result indicates that the certain specifications have not been satisfied, referring the patient to a doctor, the doctor treating the patient (col. 10, lines 8-45). Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Wolf et al. to include the repeat prescription ordering portion of Eigler et al. to ensure that the user has a new supply of the drug before the drug in the device is exhausted and to insure the proper amount of drug is being used.

16. Wolf/Eigler teaches wherein the repeat prescribed ordering portion includes a modem which automatically connects to a telephone system to electronically order a repeat prescription (col. 13-26); wherein the repeat prescription ordering portion includes a connection to an electronic network through which the repeat prescription is ordered (col. 10, lines 60-65); wherein the drug use analyzer includes a counter for counting the number of drug treatments delivered (col. 13, lines 52-67); wherein the drug analyzer includes a memory for holding the total number of drug treatments that are possible from an existing course of drug treatments (col. 13, lines 52-67); wherein the drug use analyzer includes a comparitor which compared the number of drug treatments that are possible from the memory with the number of drug treatments delivered from the counter, and generates a repeat prescription order signal when only a certain proportion of the prescribed drug remains (col. 13, lines 52-67); wherein the

repeat prescription re-ordering portion orders a repeat prescription once it received a repeat prescription order signal from the drug use analyzer (col. 10, lines 60-65); wherein the drug use analyzer includes a data carrier, including drug treatment information including the total number of drug treatments that are possible from an existing course of drug treatments (col. 13, line 52-67); wherein the memory for holding the total number of drug treatments is located in the data carrier (col. 13, lines 52-55).

17. As to claim 31, Wolf/Eigler teaches a method of prescribing a drug, comprising:

supplying a patient with a course of a number of drug treatments 623 for administering using a drug delivery device; recording the use of the drug treatments (col. 13, lines 35-39); analyzing the use of drug treatments; identifying when only a certain proportion of the drug treatments remains (col. 13, line 52-67); and submitting the recorded treatment information to a data center once only the certain proportion of the drug treatments are identified as remaining (col. 10, lines 60-65); analyzing the recorded treatment information of the data center according to a protocol in order to formulate a result which identifies whether certain specifications are satisfied, and where the result indicates that certain specification have not been satisfied, referring the patient to a doctor (col. 10, lines 8-45); issuing a course of drug treatments or a prescription for the course of treatments in response to the electronic order (col. 10, lines 60-65); wherein the electronic ordering is done via a modem connection to a telephone line (col. 13, line 23-26); wherein the electronic ordering is done via a connection to an electronic network (col. 10, lines 60-65); wherein the analyzing of the use of the drug treatments includes counting the number of drug treatments delivered

(col. 13, lines 52-67); wherein the analyzing includes the comparing of the number of drug treatments delivered with the total number of treatments supplied (col. 13, lines 52-67); further including the step of generating a repeat prescription order signal when it is identified that only a certain proportion of the drug treatments remain (col. 10, lines 60-65); and further comprising the supply of a data carrier with the course of a number of drug treatments, the data carrier bearing drug treatment information including the total number of drug treatments that are possible from the existing course of drug treatments (col. 13, lines 52-67).

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (703) 305-3285. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-19572. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MM
November 12, 2003

WEILUN LO
SUPERVISORY PATENT EXAMINER
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